

Appl. No. : 09/056,971
Filed : January 25, 2002

REMARKS

Claims 1, 21 and 58 have been amended to more clearly recite the invention. Claims 222-237 have been added. Support for the amendments and new claims can be found in the Specification as filed, for example in Figures 2, 4, 5, and 6 in which there are at least two contact points on at least one "V"-shaped element in the embodiments shown in the Figures and on page 11, lines 16-30. Support for many of the new dependent claims can be found in the claims as filed. As a result of the Claim amendments, Claims 1-74, 220-237 are submitted herewith for further prosecution.

The changes made to the Specification and Claims by the current amendment, including deletions and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

The Abstract

The abstract was objected to for being two paragraphs. Thus, the Abstract has been amended to be one paragraph as required in MPEP § 608.01(b).

Support for Claim language

The Examiner objected to the language added to the Specification and Claims in the Preliminary Amendment of May 24, 2002 as failing to specifically point out the support in the original disclosure. The following language was added to the Specification on page 9, starting on line 22: "The 2 to 4 mm (small) capsulorhexis 28 incision in the posterior chamber 18 of the capsule 21 is shown for phakoemulsification of the diseased lens." Support can be found in the Specification and claims as filed, for example, page 3, lines 8 -15 as well as Figure 14.

Support for the language added to claims 220 and 221: "wherein the optic is composed of a low modulus material" and "wherein the haptic is composed of a high modulus material" can be found in the Specification and claims as filed, for example, on pages 12-13 in which low modulus (page 13, lines 23-26) materials are disclosed for the optic, and high modulus materials are disclosed for the haptic (page 12, lines 23-page 13, line 4).

IDS

The Examiner states that the form PTO-1449 received on July 3, 2003 did not include any other pages and may have been due to a PTO mistake. Thus, the IDS which was submitted on July 3, 2003 is being re-submitted herewith in its entirety.

Rejection under 35 U.S.C. §102(b)

The Examiner has rejected Claims 1-11, 13, 15-22, 27-30, 32-48, 50, 52-59, 64-67, 69-74, and 221 under 35 U.S.C. §102(b) as being anticipated by Poler, US 4,434,515 (Poler). More specifically, the Examiner believes that the embodiment of Figures 10 and 11 in Poler includes V shaped elements each having a pair of legs and rounded and square corners as well as cleats.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ... There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Claim 1 and dependent claims:

The presently claimed invention includes a haptic having "at least one "V"-shaped element having a pair of legs and a square or rounded corner; and at least two contact points for the eye each located on one of said "V"-shaped elements". This can be seen, for example, in the embodiments in Figures 2, 5, and 6 in which one "V"-shaped element 190 has two contact points at 121. This can also be seen in an alternate embodiment in Figure 4 in which both "V"-shaped elements 190 have two contact points 121.

Poler teaches a three piece haptic which has four feet in most embodiments and three feet in one embodiment, which the Examiner believes are comparable to the claimed "V" shaped elements. Each foot as taught by Poler has only one contact point for the eye as described in column 6, line 38-44 as follows:

"Also by way of example, as for example, when the surgeon who has planned to install a lens and haptic of the assembled FIG. 8 variety, but who is confronted after initial surgery with the fact that local damage within the eye, in his opinion, precludes installation of a four-point independent haptic suspension, it is convenient to have a lens and haptic of FIG. 12 variety." (emphasis added).

Thus, there is one point of contact with the eye per foot or V-shaped element. Thus, none of the V-shaped elements described in Poler has "at least two contact points for the eye each located on one of said "V"-shaped elements". With further reference to Figure 1 in Poler, each

foot or V-shaped element 25, 26, 27, and 28 has only one contact point for the eye (25f, 26f, 27f and 28f). As stated in the reference column 6, lines 17-19 "to then allow all feet to establish their lightly outwardly loaded contact with the eye-chamber wall."

The contact points are shown in the Figures as the foot number plus the letter "f". For example with reference to Figure 1, the contact portions are 25f, 26f, 27f, and 28f. This is described in column 6 at lines 15-20 and 56-68 as follows:

"...FIGS. 4, 5 and 6), the filamentary retention being released after insertion into the eye, to then allow all feet to establish their lightly outwardly loaded contact with the eye-chamber wall." And again in column 6 at lines 56-68 as follows:

"the independently yieldable other foot regions 46f-48f remain to provide major stabilizing accommodation to more healthy tissue at the diametrically opposite region of the chamber wall."

Thus, each of the "V"-shaped elements (25-28) provide only one point of contact with the eye (25f, 26f, 27f, and 28f) and Poler does not anticipate because Poler does not teach: "at least one "V"-shaped element having a pair of legs and a square or rounded corner; and at least two contact points for the eye each located on one of said "V"-shaped elements".

Claim 39 and dependent claims:

Claim 39 and the dependent claims teach an IOL with "an attachment for said optic which permits said optic to be attached to said haptic within the eye". Poler does not teach all of the claimed elements because Poler et al does not teach that the optic can be attached to the haptic within the eye. The optic of Poler fits into the 2 piece haptic in a sandwich method. With reference to Figures 1-3, the first part of the haptic (as shown in Figure 2) is laid down, then the optic (10 in Figure 1) is set on this part of the haptic, and finally the second part of the haptic (as shown in Figure 3) is laid on top of the optic, sandwiching the optic between the two parts of the haptic and creating the IOL shown in Figure 1. This construction is then placed into the eye. It is clear that the IOL of Poler is intended to be assembled before implantation into the eye because the sandwiching method of assembly would be impossible within the eye and, for example, in column 6, lines 38-40 Poler teaches that "Also by way of example, as for example, when the surgeon who has planned to install a lens and haptic of the assembled FIG. 8 variety..."

Further, in column 6, lines 9-19 Poler teaches that, "These structures will also be understood to lend themselves to simple techniques of implantation, as by use of suture or the like filament to draw all foot formations to their most compliantly stressed radially inward

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condition of minimum out radius (for example by threading the releasable filament through apertures 35g...38g of FIGS. 4, 5 and 6), the filamentary retention being released after insertion into the eye, to then allow all feet to establish their lightly outwardly loaded contact with the eye-chamber wall." This teaches that the assembled structure is placed in the eye and then the tightness of the structure is loosened to allow it to be fit to the specific size of the eye.

Thus, Poler et al. does not anticipate independent Claim 39, because Poler et al does not teach an IOL which allows the "optic to be attached to said haptic within the eye".

Rejection under 35 U.S.C. §103(a)

The Examiner has rejected Claims 12, 14, 23-26, 31, 49, 51, 60-63, 68, and 220 under 35 U.S.C. §103(a) as being unpatentable over Poler, US 4,434,515 (Poler). The Examiner believes that additions such as tinted eyelets, materials, and property ranges would have been obvious to one of skill in the art.

The law is clear that three basic criteria must be met to establish a *prima facie* case of obviousness: (MPEP ¶2143):

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references, when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (*In re Vaack*, 947 F.2d 488, 20 USPQ2d 1440 (Fed. Cir. 1991)).

As stated above in the rejections under 35 U.S.C. §102(b), Poler does not anticipate the invention because Poler et al does not teach all of the claimed elements. Thus, even if the additions such as tinted eyelets, materials, and property ranges would have been obvious to one of skill in the art, Poler does not render the claimed invention obvious because Poler does not teach or suggest all of the claim limitations.

New Claims 222 and 223

New Claims 222, is directed to an IOL in which the legs are sufficiently flexible to "bend up to or over the other". Poler et al. does not teach that the legs are sufficiently flexible to bend up to or over the other". Applicants would like the Examiner to note that for the same reasons as discussed above in the anticipation rejection of Claims 39, new Claim 223 is not anticipated by the Poler et al patent.

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Conclusion

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

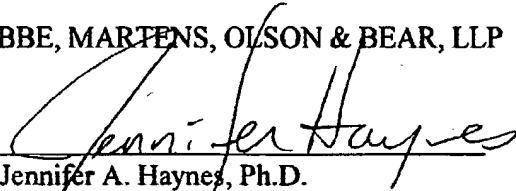
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Sept. 8, 2004

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